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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,741	10/06/2000	IB Mendel-Hartvig	10806-128	1595

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,741	MENDEL-HARTVIG ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 29, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 11-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 11-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed December 29, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 6, 11-18, 20-25 and 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al (WO 97/09620) in view of Van Deusen et al (US 5,132,097).

Rylatt et al disclose a method and device for the quantitative determination of a target analyte in a test sample. Rylatt et al disclose a lateral flow permeable medium (matrix) comprising a calibration zone and a detection zone. Rylatt et al disclose the application zone for labeled calibration agent and labeled analyte agent (Reactant *) is located upstream of the calibration zone. Rylatt et al disclose a test (detection) zone downstream of the calibration zone (Figures 2,5,8). Rylatt et al also disclose a non-diffusibly attached analyte receptor (Reactant I) in the detection zone. Rylatt et al disclose that the calibrator or calibrator agent can be immobilized in the calibration zone. Rylatt et al disclose that the comparison of the signals generated in the test (detection) zone and the calibration zone is used to determine the concentration of analyte in the sample. Rylatt et al disclose that the lateral flow medium can be read

visually or can be read instrumentally (p. 27). Rylatt et al disclose that the target analyte can be an antibody (p. 5). Rylatt et al disclose the invention comprises a kit for use in the methods disclosed by Rylatt. Rylatt et al disclose that the calibration agent can be a calibration agent, which has high affinity for the specific binding partner (p. 9).

Rylatt et al differ from the instant invention in failing to teach the calibrator and the analyte biospecifically bind to Reactant* by equivalent binding sites.

Van Deusen et al disclose a test strip comprising a standard area (calibration zone) and test area (detection zone). Van Deusen et al disclose reactant B (calibrator) (col 4, Figures 1-3) immobilized to the calibration zone. Van Deusen et al disclose labeled reagent, which binds to both the calibrator and the analyte (col 4, lines 34-54). Van Deusen et al disclose that the use of this labeled reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip and provides for a method in which it is not necessary for the reactants to come to equilibrium, but instead allows for a time base to be established for the allowed reaction time for the formation of the complex in the test area to which the number of complexes and standard (calibrator) may be compared (col 4, lines 45-54).

It would have been obvious to one of ordinary skill in the art to incorporate calibration agents and labeled reagents as taught by Van Deusen et al into the method and device of Rylatt et al because Rylatt et al is generic with respect to the calibrator agent and labeled agent. Further, Van Deusen et al shows that the use of this labeled reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip and provides for a method in which it is not necessary

for the reactants to come to equilibrium, but instead allows for a time base to be established for the allowed reaction time for the formation of the complex in the test area to which the number of complexes and standard (calibrator) may be compared. It would also provide the advantage of reducing the number of reagents used for the

3. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al and Van Deusen et al in view of Self et al (US 4,446,231).

See above for teachings of Rylatt et al and van Deusen et al.

Rylatt et al and Van Deusen et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

4. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al and Van Deusen et al in view of Weng et al (US 4,740,468).

See above for teachings of Rylatt et al and Van Deusen et al.

Rylatt et al and Van Deusen et al differ from the instant invention in failing to teach an immobilized reactant that is biospecific to a second reactant which in turn has biospecific affinity to the analyte.

Weng et al disclose the use of a specific binding partner that is biospecific to a second binding partner, which is in turn specific for the analyte (col 2, lines 47-53). Weng et al disclose that is useful for determining the presence of an analyte in a sample suspected of containing the analyte (col 2, lines 39-41) and also allows for the determination of a plurality of analytes in a test solution (col 3, lines 20-27).

It would have been obvious to one of ordinary skill in the art to incorporate the use of an immobilized specific binding partner (reactant) as taught by Weng et al into the modified method and device of Rylatt et al because Weng et al shows that this specific binding partner allows for the determination of a plurality of analytes in a test solution.

Response to Arguments

5. Applicant's arguments filed December 29, 2003 have been fully considered but they are not persuasive.

Applicant argues that Rylatt et al discloses a device which includes a test zone 204 arranged between calibration zones 210 and 211 (fig 2) and thus, all of the detection or test zones are not downstream of all the calibration zones as required by

claim 20, but interspersed therein. Examiner agrees that Rylatt et al teaches a test zone arranged between calibration zones 210 and 211. However, Claim 20 only requires the presence of one calibration zone (i.e. Claim 20, step (i) one or more calibration zones comprising a calibrator, or binder for the calibrator, which is firmly anchored to the matrix) and one detection zone (i.e. Claim 20, step (iii) one or more detection zones, all of the detection zones being downstream of all of the calibrator zones). Rylatt clearly teaches one calibration zone (210) and one detection zone (204) downstream of the one calibration zone. Therefore, since the claim only requires one calibration zone and one detection zone, Rylatt et al meets the limitations of claim 20 and therefore reads on the instantly recited claims.

6. Applicant argues that Rylatt et al does not teach or suggest a method or device employing Reactant* binding to both calibrator and analyte as recited in claim 1. This is not found persuasive because Examiner has not relied upon Rylatt for teachings this limitation but rather has relied upon Van Deusen et al for teaching calibration agents and labeled reagents that bind to both calibrator and analyte and the advantages of using such reagents. Applicant argues that only in hindsight of the presently claimed methods would one of ordinary skill in the art be motivated to combine the teachings of Van Deusen et al. This is not found persuasive because Van Deusen et al shows that the use of this labeled reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip (same as Rylatt) and provides for a method in which it is not necessary for the reactants to come to equilibrium, but instead allows for a time base to be established for the allowed reaction time for the

formation of the complex in the test area to which the number of complexes and standard (calibrator) may be compared. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that the tertiary references Self et al and Weng et al do not resolve the deficiencies of Rylatt et al and Van Deusen et al and thus the references have been overcome. This is not found persuasive because it is the Examiner's position that Rylatt et al and Van Deusen et al read on the instantly recited claims and therefore the combination of the tertiary references with Rylatt and Van Deusen is proper and reads on the instantly recited claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary W. Counts
Examiner
Art Unit 1641
March 25, 2004

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04/01/04